

## PATENT APPLICATION

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91103

Harumi MINEKAWA, et al.

Appln. No.: Unassigned  
(§371 entry of PCT/JP2004/008355)

Confirmation No.: Unassigned

Group Art Unit: Unassigned

Filed: December 22, 2005

Examiner: Unassigned

For: METHOD FOR DETECTING SARS CORONAVIRUS

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

Applicants meet the requirements for a concise explanation of foreign language documents under 37 C.F.R. § 1.98(a)(3) in the following manners. First, Applicants enclose herewith a copy of the International Search Report, indicating the degree of relevance of each

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IAP9 Rec'd PCT/PTO 22 DEC 2005

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§371 entry of PCT/JP2004/008355

Q91103

document. Additionally, EP 1020534 A1 (document (3)) and EP 1327679 A1 (document (4)) are enclosed, which are English language versions of WO 00/28082 A1 (document (1)) and WO 02/24902 A1 (document (2)), respectively. Further, English language translations of documents (7), (9) and (12) are being submitted herewith, as well as English language abstracts of documents (11), (16) and (18).

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,



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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: December 22, 2005

Substitute for Form 1449 A &amp; B/PTO

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

1

of

2

Application Number	\$371 entry PCT/JP2004/008355
Confirmation Number	Unknown
Filing Date	December 22, 2005
First Named Inventor	Harumi MINEKAWA
Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	Q91103

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
		US			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
	(1)	WO	00/28082	A1	05-18-2000	Eiken Chemical Co., Ltd	
	(2)	WO	02/24902	A1	03-28-2002	Eiken Chemical Co., Ltd	
	(3)	EP	1020534	A1	07-19-2000	Eiken Chemical Co., Ltd	
	(4)	EP	1327679	A1	07-16-2003	Eiken Chemical Co., Ltd	
	(5)	CN	1458281	A	11-26-2003	HUANQIU ZHONGJIA BIOLOG SCIENC	Abstract

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
	(6)	The World Health Organization Update 49-SARS case fatality ratio, incubation period, May 7, 2003, Case fatality ratio (date of search: June 24, 2003), URL: <a href="http://www.who.int/csr/sars/archive/2003_05_07/a/en">http://www.who.int/csr/sars/archive/2003_05_07/a/en</a>	
	(7)	"SARS: Diagnostic test methods" (April 29, Revision 4-1), date of search: June 24, 2003, URL: <a href="http://idsc.nih.gov/journals/urgent/update41-No.1.html">http://idsc.nih.gov/journals/urgent/update41-No.1.html</a> , the Infectious Disease Surveillance Center (IDSC), the National Institute of Infectious Diseases	Yes
	(8)	C. Drosten, et al., "Identification of a Novel Coronavirus in Patients with Severe Acute Respiratory Syndrome", N. England J. Med. May 15, 2003, Vol. 348, No. 20, pp 1967-1976	
	(9)	"SARS coronavirus gene detection using an RT-PCR method" (date of renewal: May 16, 2003), date of search: June 24, 2003, URL: <a href="http://idsc.nih.gov/journals/urgent/update56-b.html">http://idsc.nih.gov/journals/urgent/update56-b.html</a> , the Laboratory of Influenza Viruses, Department of Virology III, the Infectious Disease Surveillance Center (IDSC), the National Institute of Infectious Diseases	Yes
	(10)	T. Notomi, et al., "Loop-mediated isothermal amplification of DNA.", Nucleic Acids Research, (2000), Vol. 28, No. 12, page 63 (i-vii)	
	(11)	J. Yang, et al., "Clinical Detection of polymerase gene of SARS-associated coronavirus", Journal of First Military Medical University, Department of Infectious Diseases, Nanfang Hospital, China, May 2003, Vol. 23, No. 5, pp. 424-427	Abstract
	(12)	Eiken Chemical Co., Ltd. "Eiken Kagaku, LAMP-ho o Riyo Shita SARS Corona Virus Kenshutsu Shiyaku Kaihatsu de Nagasaki Daigaku Nettai Igaku Kenkyusho to Kyodo Kenkyu o Kaishi.", [online], June 19, 2003, [retrieved on August 3, 2004], retrieved from the Internet: <URL: <a href="http://www.tm.nagasaki-u.ac.jp/japanese/SARS_news_release.PDF">http://www.tm.nagasaki-u.ac.jp/japanese/SARS_news_release.PDF</a> >	Yes
	(13)	GeneBank NC_004718.3, June 23, 2003, M.A. MARRA, et al., SARS coronavirus, complete genome, [retrieved on August 3, 2004], Retrieved from the Internet: <URL: <a href="http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?30271926:OLD12:897150">http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?30271926:OLD12:897150</a> >	

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				Application Number	Based on PCT/JP2004/008355
				Confirmation Number	Unknown
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				First Named Inventor	Harumi MINEKAWA
				Art Unit	Unknown
				Examiner Name	Unknown
				Attorney Docket Number	Q91103
Sheet	2	of	2		

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	(14)	Fujitsu Ltd., "PRESS RELEASE LAMP-ho no tameno Senyo Primer Sekkei Shien Service o Web de Teikyo LAMP-ho Seihin Hanbai no eMarket Place mo Unyo Kaishi.", [online], May 16, 2002, [retrieved on August 3, 2004], Retrieved from the Internet: <URL: <a href="http://pr.fujitsu.com/jp/news/2002/05/16-1.html">http://pr.fujitsu.com/jp/news/2002/05/16-1.html</a> >	
	(15)	H. T. C. Thai, et al., "Development and Evaluation of a Novel Loop-Mediated Isothermal Amplification Method for Rapid Detection of Severe Acute Respiratory Syndrome Coronavirus", Journal of Clinical Microbiology, May 2004, Vol. 42, No. 5, pp. 1956-1961	
	(16)	B. ZHOU, et al., "Identification and molecular cloning and sequence analysis of a novel coronavirus from patients with SARS by RT-PCR", Chinese J. Exp. Clin. Virol., (June, 2003), Vol. 17, No. 2, pages 137-139, (abstract)	Abstract
	(17)	L. L. M. POON, et al., "Rapid Detection of Severe Acute Respiratory Syndrome (SARS) Coronavirus by a Loop-Mediated Isothermal Amplification Assay., Clinical Chemistry, (June 28, 2004), Vol. 50, No. 6, pp. 1050 to 1052	
	(18)	Teruo KIRIKAE, "Current Situation of SARS corona virus test methods and future prospects", Antibiotics & Chemotherapy, (December, 2003), Vol. 20, No. 1, pp. 63-69	Abstract

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